



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: July 15, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Nature & Health Co Recall

SUGGESTED

ACTION: Unclassified Recall; Nature & Health Co's LibieXtreme, Y-4ever, Libimax X Liquid, Powermania Liquid and Capsule, Herbal Disiac; Information provided in case of consumer inquiries.

From the information provided by FDA, the products being recalled were NOT distributed in the State of Indiana, but were in our neighboring States of Illinois and Ohio. None of the active drug ingredients are listed on the product labels. The undeclared ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nature & Health Co. Issues Voluntary Nationwide Recall of Six Male Enhancement Products Marketed as Dietary Supplements

Contact:

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FOR IMMEDIATE RELEASE - Brea, CA – July 15, 2007 – Opteron 1 Inc. dba Nature & Health Co., announced today that it is conducting a voluntary nationwide recall of the company's five supplement products sold under the following names: LibieXtreme, Y-4ever, Libimax X Liquid, Powermania Liquid and Capsule, Herbal Disiac.

The Company has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis by FDA of these five samples found they contains either tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED) , its analog aminotadalafil, or the analog of sildenafil, an active ingredient of another FDA-approved ED drug, making these products unapproved drugs. None of the active drug ingredients are listed on the product labels. The undeclared ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

The six recalled products listed below were distributed in retail stores in California, Georgia, Illinois, Texas, and Ohio.

Brand	Size	Active Pharmaceutical Ingredient
LibieXtreme	1 Capsule Packet	Aminotadalafil
Y-4ever	1 Capsule Packet	Sulfoildenafil
Libimax X Liquid	1 Fl. Oz. Packet	Aminotadalafil
Powermania liquid	1 Fl. Oz. Packet	Sulfoildenafil
Herbal Disiac	40 capsule bottle	Tadalafil
Powermania	1 Capsule Packet	Sulfoildenafil

Customers who have these products in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

Nature & Health Co. is committed to providing accurate information about its products because of concern for the health and safety of consumers. Nature & Health Co. is working with the FDA in the recall process. It sincerely regrets any inconvenience to customers.

No illnesses have been reported to the company to date in connection with these products.

Consumers should return any unused products, for a refund of the full purchase price or price for the unused portion, to the retail location where they were purchased or contact Nature & Health directly at (714) 671-0016 Monday – Friday, 8am to 5pm or by email at sales@naturehealth.com to receive further instructions for returning the product or with any questions.

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